



Senate

General Assembly

January Session, 2013

File No. 340

Senate Bill No. 857

Senate, April 4, 2013

The Committee on Insurance and Real Estate reported through SEN. CRISCO of the 17th Dist., Chairperson of the Committee on the part of the Senate, that the bill ought to pass.

AN ACT CONCERNING THE USE OF STEP THERAPY FOR AND OFF-LABEL PRESCRIBING OF PRESCRIPTION DRUGS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. Section 38a-510 of the general statutes is repealed and the
2 following is substituted in lieu thereof (*Effective January 1, 2014*):

3 (a) No individual health insurance policy [issued on an individual
4 basis, whether issued] delivered, issued for delivery, renewed,
5 amended or continued in this state by an insurance company, a
6 hospital service corporation, a medical service corporation or a health
7 care center, [which] that provides coverage for prescription drugs may
8 require any person covered under such policy to obtain prescription
9 drugs from a mail order pharmacy as a condition of obtaining benefits
10 for such drugs.

11 [(b) The provisions of this section shall apply to any such policy
12 delivered, issued for delivery, renewed, amended or continued in this
13 state on or after July 1, 2005.]

14 (b) No such policy may require any person covered under such
15 policy to use any alternative brand name prescription drugs or over-
16 the-counter drugs prior to using a brand name prescription drug
17 prescribed by a licensed physician, except that such policy may require
18 any person covered under such policy to use a therapeutically-
19 equivalent generic drug prior to using a brand name prescription drug
20 prescribed by a licensed physician.

21 (c) (1) If such policy requires the use of step therapy, such policy
22 may not (A) require failure on the same prescription drug more than
23 once, or (B) impose a copayment greater than the lowest cost
24 copayment for preferred drugs in the same class on any person
25 covered under such policy who has satisfied, in the judgment of the
26 prescribing physician, the step therapy requirements of such policy.
27 For purposes of this subsection, "step therapy" means protocols that
28 establish specific sequences for the prescribing of prescription drugs
29 for a specified medical condition.

30 (2) Nothing in subdivision (1) of this subsection shall be construed
31 to prohibit the use of tiered copayments for any person covered under
32 such policy who is not subject to the use of step therapy.

33 Sec. 2. Section 38a-544 of the general statutes is repealed and the
34 following is substituted in lieu thereof (*Effective January 1, 2014*):

35 (a) No group medical benefits contract [on a group basis, whether
36 issued] delivered, issued for delivery, renewed, amended or continued
37 in this state by an insurance company, a hospital service corporation, a
38 medical service corporation or a health care center, [which] that
39 provides coverage for prescription drugs may require any person
40 covered under such contract to obtain prescription drugs from a mail
41 order pharmacy as a condition of obtaining benefits for such drugs.

42 [(b) The provisions of this section shall apply to any such medical
43 benefits contract delivered, issued for delivery or renewed in this state
44 on or after July 1, 1989.]

45 (b) No such policy may require any person covered under such
46 policy to use any alternative brand name prescription drugs or over-
47 the-counter drugs prior to using a brand name prescription drug
48 prescribed by a licensed physician, except that such policy may require
49 any person covered under such policy to use a therapeutically-
50 equivalent generic drug prior to using a brand name prescription drug
51 prescribed by a licensed physician.

52 (c) (1) If such policy requires the use of step therapy, such policy
53 may not (A) require failure on the same prescription drug more than
54 once, or (B) impose a copayment greater than the lowest cost
55 copayment for preferred drugs in the same class on any person
56 covered under such policy who has satisfied, in the judgment of the
57 prescribing physician, the step therapy requirements of such policy.
58 For purposes of this subsection, "step therapy" means protocols that
59 establish specific sequences for the prescribing of prescription drugs
60 for a specified medical condition.

61 (2) Nothing in subdivision (1) of this subsection shall be construed
62 to prohibit the use of tiered copayments for any person covered under
63 such policy who is not subject to the use of step therapy.

64 Sec. 3. Section 38a-492b of the general statutes is repealed and the
65 following is substituted in lieu thereof (*Effective January 1, 2014*):

66 (a) Each individual health insurance policy delivered, issued for
67 delivery, renewed, amended or continued in this state, that provides
68 coverage for prescribed drugs approved by the federal Food and Drug
69 Administration for treatment of certain types of cancer or disabling or
70 life-threatening chronic diseases, shall not exclude coverage of any
71 such drug on the basis that such drug has been prescribed for the
72 treatment of a type of cancer or a disabling or life-threatening chronic
73 disease for which the drug has not been approved by the federal Food
74 and Drug Administration, provided the drug is recognized for
75 treatment of the specific type of cancer or a disabling or life-
76 threatening chronic disease for which the drug has been prescribed in
77 one of the following established reference compendia: (1) The U.S.

78 Pharmacopoeia Drug Information Guide for the Health Care
79 Professional (USP DI); (2) The American Medical Association's Drug
80 Evaluations (AMA DE); or (3) The American Society of Hospital
81 Pharmacists' American Hospital Formulary Service Drug Information
82 (AHFS-DI).

83 (b) Such policy shall not require, as a condition of coverage, the use
84 of any prescription drug for a condition for which such drug has not
85 been approved by the federal Food and Drug Administration, unless
86 such drug is prescribed by such person's treating health care provider.

87 ~~[(b)]~~ (c) Nothing in subsection (a) of this section shall be construed
88 to require coverage for any experimental or investigational drugs or
89 any drug which the federal Food and Drug Administration has
90 determined to be contraindicated for treatment of the specific type of
91 cancer or disabling or life-threatening chronic disease for which the
92 drug has been prescribed.

93 ~~[(c)]~~ (d) Except as specified, nothing in this section shall be
94 construed to create, impair, limit or modify authority to provide
95 reimbursement for drugs used in the treatment of any other disease or
96 condition.

97 Sec. 4. Section 38a-518b of the general statutes is repealed and the
98 following is substituted in lieu thereof (*Effective January 1, 2014*):

99 (a) Each group health insurance policy delivered, issued for
100 delivery, renewed, amended or continued in this state, that provides
101 coverage for prescribed drugs approved by the federal Food and Drug
102 Administration for treatment of certain types of cancer or disabling or
103 life-threatening chronic diseases, shall not exclude coverage of any
104 such drug on the basis that such drug has been prescribed for the
105 treatment of a type of cancer or a disabling or life-threatening chronic
106 disease for which the drug has not been approved by the federal Food
107 and Drug Administration, provided the drug is recognized for
108 treatment of the specific type of cancer or a disabling or life-
109 threatening chronic disease for which the drug has been prescribed in

110 one of the following established reference compendia: (1) The U.S.
 111 Pharmacopoeia Drug Information Guide for the Health Care
 112 Professional (USP DI); (2) The American Medical Association's Drug
 113 Evaluations (AMA DE); or (3) The American Society of Hospital
 114 Pharmacists' American Hospital Formulary Service Drug Information
 115 (AHFS-DI).

116 (b) Such policy shall not require, as a condition of coverage, the use
 117 of any prescription drug for a condition for which such drug has not
 118 been approved by the federal Food and Drug Administration, unless
 119 such drug is prescribed by such person's treating health care provider.

120 ~~[(b)]~~ (c) Nothing in subsection (a) of this section shall be construed
 121 to require coverage for any experimental or investigational drugs or
 122 any drug which the federal Food and Drug Administration has
 123 determined to be contraindicated for treatment of the specific type of
 124 cancer or a disabling or life-threatening chronic disease for which the
 125 drug has been prescribed.

126 ~~[(c)]~~ (d) Except as specified, nothing in this section shall be
 127 construed to create, impair, limit or modify authority to provide
 128 reimbursement for drugs used in the treatment of any other disease or
 129 condition.

This act shall take effect as follows and shall amend the following sections:		
Section 1	January 1, 2014	38a-510
Sec. 2	January 1, 2014	38a-544
Sec. 3	January 1, 2014	38a-492b
Sec. 4	January 1, 2014	38a-518b

INS *Joint Favorable*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 14 \$	FY 15 \$
State Comptroller - Fringe Benefits	GF, TF - Preclude Savings	\$4.2 to \$9.2 million	\$4.2 to \$9.2 million
The State	Indeterminate	Indeterminate	Indeterminate

Municipal Impact:

Municipalities	Effect	FY 14 \$	FY 15 \$
Various Municipalities	STATE MANDATE - Cost	Potential	Potential

Explanation

The bill may preclude savings of \$4.2 to \$9.2 million¹ to the state employee and retiree health plan ("the state plan").² The state plan does not currently require the use of step-therapy; however the plan has considered step-therapy as a cost savings measure.

Sections 3 and 4 do not result in a fiscal impact to the state plan. The state plan does not cover medication which is prescribed for a condition for which it has not received FDA approval. The bill does not require the state plan to cover such prescriptions.

¹ State Health Plan Pharmacy Benefit Manager

² The state employee and retiree health plan is currently self-insured. Pursuant to federal law, self-insured health plans are exempt from state health mandates. However, the state has traditionally adopted all state health mandates.

Municipal Impact

The bill will increase costs to certain fully insured, municipal plans which require the use of 1) step-therapy and 2) prescription drugs for conditions where the drug is not yet approved by the FDA and not prescribed by the individual's treating physician. The coverage requirements may result in increased premium costs when municipalities enter into new health insurance contracts after January 1, 2014. In addition, many municipal health plans are recognized as "grandfathered" health plans under the Patient Protection and Affordable Care Act (PPACA).³ It is unclear what effect the adoption of certain health mandates will have on the grandfathered status of certain municipal plans under PPACA.⁴ Pursuant to federal law, self-insured health plans are exempt from state health mandates.

The State and PPACA

Lastly, PPACA requires that, effective January 1, 2014; all states must establish a health benefit exchange, which will offer qualified health plans that must include a federally defined essential health benefits package (EHB). The federal government is allowing states to choose a benchmark plan to serve as the EHB until 2016 when the federal government is anticipated to revisit the EHB.

While states are allowed to mandate benefits in excess of the EHB, the federal law requires the state to defray the cost of any such additional mandated benefits for all plans sold in the exchange. The extent of these costs will ultimately depend on the mandates included in the federal essential benefit package, which have not yet been determined. State mandated benefits enacted after December 31, 2011

³ Grandfathered plans include most group insurance plans and some individual health plans created or purchased on or before March 23, 2010.

⁴ According to the PPACA, compared to the plans' policies as of March 23, 2010, grandfathered plans who make any of the following changes within a certain margin may lose their grandfathered status: 1) Significantly cut or reduce benefits, 2) Raise co-insurance charges, 3) Significantly raise co-payment charges, 4) Significantly raise deductibles, 5) Significantly lower employer contributions, and 5) Add or tighten annual limits on what insurer pays. (www.healthcare.gov)

cannot be considered part of the EHB for 2014-2015 unless they are already part of the benchmark plan.⁵ However, neither the agency nor the mechanism for the state to pay these costs has been established.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

⁵ Source: Dept. of Health and Human Services. *Frequently Asked Questions on Essential Health Benefits Bulletin* (February 21, 2012).

OLR Bill Analysis**SB 857*****AN ACT CONCERNING THE USE OF STEP THERAPY FOR AND OFF-LABEL PRESCRIBING OF PRESCRIPTION DRUGS.*****SUMMARY:**

This bill prohibits individual and group health insurance policies from requiring anyone covered under them to use any alternative brand name prescription or over-the-counter drugs before using a brand name prescription drug prescribed by a licensed physician. But, the policy may require the covered person to use a therapeutically-equivalent generic drug before using a brand name drug prescribed by a licensed physician.

Under the bill, if a policy requires the use of step therapy, it may not (1) require failure on the same prescription drug more than once or (2) impose a copayment greater than the lowest cost copayment for preferred drugs in the same class on any person covered under the policy who has satisfied, in the prescribing physician's judgment, the step therapy requirements of the policy. Under the bill, "step therapy" are protocols that establish specific sequences for prescribing drugs for a specified medical condition.

The bill does not prohibit using tiered copayments for any person covered under such policy who is not subject to the use of step therapy.

The bill bars certain policies from requiring, as a condition of coverage, the use of any prescription drug for a condition for which it has not been approved by the federal Food and Drug Administration, unless it is prescribed by the person's treating health care provider. This provision applies to individual and group health insurance policies that cover prescribed drugs approved by the Food and Drug

Administration to treat cancer or a life-threatening chronic disease.

The bill also makes minor and technical changes.

EFFECTIVE DATE: January 1, 2014

BACKGROUND

Related Federal Law

The Affordable Care Act (P. L. 111-148) allows a state to require health plans sold through its exchange to offer benefits beyond those already included in its “essential health benefits,” but the act requires the state to defray the cost of these additional benefits. The requirement applies to mandates enacted after December 31, 2011. As a result, the state would be required to pay the insurance carrier or enrollee to defray the cost of any new benefits mandated after this date.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable

Yea 10 Nay 8 (03/19/2013)